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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SAUNDERS, DAVID A

ART UNIT PAPER NUMBER

1644

DATE MAILED: 12/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

868,666

Applicant(s)

ISLAM et al.

Examiner

SAUNDERS

Group Art Unit

1644

--The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address--

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

- ☒ Responsive to communication(s) filed on 8/22/03 & 9/17/03.
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- ☒ Claim(s) 13-38 is/are pending in the application.
- ☐ Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☒ Claim(s) 13-16, 18-38 is/are allowed.
- ☒ Claim(s) 17 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

### Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

Office Action Summary

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Amendment of 9/17/03 has been entered. Claims 13-38 are pending and under examination. The amendment has entered no new matter.

Examiner notes that in the previous Office action, at page 5, line 3, "13" should have read as -13-15, 18-21, 26-30, 32 and 37-38--. All these claims were addressed in the body of the rejection.

The amendment has overcome previously stated issues as follows:

The rejection of claims under 35 USC 112, 1st paragraph.

The prior art rejections of claims 13-16 and 18-38 based upon Etcheverry et al, Fischer et al and Feld.

The following rejections of record are maintained or modified as follows:

Claim 17 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Etcheverry et al.

Teachings of Etcheverry et al have been noted previously. As noted, Etcheverry et al teach production of glycoproteins in a medium having "about 0.1 mM" alkanolic acid (e.g. col. 24, line 46) as a lower limit. Instant claim 17 merely calls for "subculturing" at an alkanolic acid concentration of less than 0.1mM. Since teachings of "about 0.1 mM" in the reference overlap "less than 0.1 mM" in the claim, the recited range does not distinguish.

Further, recitation of "subculturing" does not distinguish. Any cell line, such as a genetically engineered CHO cell or a hybridoma, can only be maintained in a closed culture medium for a limited time and must be recultured (or "subcultured") in another batch. Note Etcheverry et al at col. 10, line38-col. 11, line 38, for example.

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As the examiner sees it, applicant could practice the method of claim 17 by maintaining a first generation culture under the conditions recited in base claim 13 (which is patentable over the reference) and then culture under the conditions recited in dependent claim 17 for hundreds of subsequent generations. Since one observing a culturing process of one of these subsequent generations could not determine what the culture conditions might have been in the first generation culture (The subsequently cultured cells would be the same, and the medium would be the same as taught by the reference), what applicant would be doing at the stage of culturing any subsequent generation would be inherently the same as or, at the least, indistinguishable from the prior art.

Claim 17 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fischer et al.

Teachings of Fischer et al have been noted previously. As noted, Fisher et al teach production of proteins in a medium having "about 0.1 mM" alkanolic acid (e.g. page 9, line 37) as a lower limit. Instant claim 17 is rejected following the same rationale stated supra for Etcheverry et al.

Claim 17 is not rejected over Feld because Feld does not recite "about" before "0.1mM".

Applicant's arguments filed 8/22/03 and 9/17/03 have been fully considered but they are not persuasive.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Saunders, PhD whose telephone number is 703-308-3976. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on 703-308-3973. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

*David A Saunders*  
DAVID SAUNDERS  
PRIMARY EXAMINER  
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